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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SCOTT EDWARD OSBORNE, GEORGE ENDEL DECKNER,
THOMAS JAMES KLOFTA, and VICTOR NICHOLAS VEGA

Appeal 2008-003856
Application 10/804,381
Technology Center 1600

Decided: August 28, 2009

Before DONALD E. ADAMS, DEMETRA J. MILLS, and ERIC GRIMES,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition and article for applying a skin care agent. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification discloses a composition that “provides a means of delivering skin care actives to the skin from an oil-based composition” (Spec. 5: 14-15).

Claims 1-9 and 11-19 are pending and on appeal. Appellants have argued the claims in three groups; the claims in each group stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claims 1, 14, and 17 are representative and read as follows:

1. A release composition comprising:
 - (4) from about $10^{-4}\%$ to about 20%, by weight of the release composition, of at least one skin care active, said skin care active comprising chitosan;
 - (5) from about 0.1% to about 60 %, by weight of the release composition, of a release agent; and
 - (6) from about 0.1% to about 95%, by weight of the release composition, of a barrier protectant, said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms;
wherein the release composition is semi-solid or solid at 20°C and at least partially transferable to a target skin surface.
14. An article, comprising:
 - c. a dispensing means; and
 - d. a release composition applied to at least a portion of the dispensing means, the release composition comprising:
 - (4) from about $10^{-4}\%$ to about 20%, by weight of the release composition, of at least one skin care active, said skin care active comprising chitosan;
 - (5) from about 0.1% to about 60 %, by weight of the release composition, of a release agent; and
 - (6) from about 0.1% to about 95 %, by weight of the release composition, of a barrier protectant, said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms;

wherein the release composition is semi-solid or solid at 20°C and at least partially transferable to a wearer's skin.

17. A method for effectively delivering one or more skin care actives to skin, comprising:

- (a) applying to the skin an article comprising a dispensing means and a release composition disposed on at least a portion of the dispensing means;
- (b) transferring at least a portion of the release composition to the skin;
- (c) exposing the release composition to moisture; and
- (d) releasing one or more skin care active ingredients from the release composition;

wherein the release composition is semi-solid or solid at 20°C and comprises:

- (1) from about 10⁴% to about 20%, by weight of the release composition, of at least one skin care active, said skin care active comprising chitosan;
- (2) from about 0.1% to about 60 %, by weight of the release composition, of a release agent; and
- (3) from about 0.1% to about 95 %, by weight of the release composition, of a barrier protectant, said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms.

OBVIOUSNESS

Issue

The Examiner has rejected claims 1-9 and 11-19 under 35 U.S.C. § 103(a) as obvious in view of Roe¹ and Johansson² (Answer 3). The Examiner finds that Roe discloses a composition comprising the ingredients of claim 1 except for a skin care active comprising chitosan (Answer 3) and that "Johansson teaches skin composition containing chitosan . . . for

¹ Roe et al., US 5,643,588, issued Jul. 1, 1997.

² Johansson et al., US 6,562,802 B2, issued May 13, 2003.

successful binding of antiallergenic substances such as EDTA” (*id.* at 4). The Examiner concludes that it would have been obvious to add Johansson’s chitosan/EDTA combination to Roe’s lotion “because Johansson suggests that chitosan has superior features to make it a skin or mucus membrane protector when combined with an anti-allergen and it is very effective in protecting skin during therapeutic treatments with anti-viral, anti-bacterial treatment” (*id.*).

Appellants contend that the references would not have made obvious the composition of claim 1 because a person of ordinary skill in the art would not have seen a reason to combine Johansson’s chitosan with Roe’s lotion composition (Appeal Br. 4-7).

The issue presented is: Did the Examiner err in concluding that it would have been obvious to a worker of ordinary skill to combine Johansson’s skin care active comprising chitosan with Roe’s composition?

Findings of Fact

1. The Specification discloses that a “release composition suitable for the present invention comprises one or more skin care actives, a release agent and a barrier protectant” (Spec. 5: 18-19).

2. The Specification discloses that “[s]kin care actives suitable for use herein include, but are not limited to skin conditioning agents, . . . antimicrobials, humectants, vitamins, skin protectants and/or skin soothing agents” (*id.* at 7: 1-4).

3. The Specification discloses that the “skin care actives in the present invention should preferably include at least one of the following: allantoin, . . . chitosan, and mixtures thereof” (*id.* at 8: 3-6).

4. The Specification discloses that the “release agents suitable for use herein typically have a HLB of at least 3, which include, but are not limited to, nonionic surfactants, polymeric surfactants, and mixtures thereof. The term ‘HLB’ refers to the hydrophilic lipophilic balance.” (*Id.* at 10: 3-5.)

5. The Specification discloses that “[n]onionic surfactants useful herein include” (Spec. 10: 15) commercially available Brij® nonionic surfactants (*id.* at 11: 6-10) and “commercially available ethoxylated materials includ[ing] TWEEN® (ethoxylated sorbitan mono-, di- and/or tri-esters of C12 to C18 fatty acids with an average degree of ethoxylation of from about 2 to about 20)” (*id.* at 12: 22-24).

6. The Specification discloses that “[p]araffin waxes are typically linear alkanes (i.e., saturated hydrocarbons) having about 16-50 carbons. The most commonly used paraffin wax in skin care compositions is petrolatum” (*id.* at 14: 6-9).

7. Roe discloses a “diaper having a lotion coating on the outer surface of the topsheet that is semisolid or solid at ambient temperatures (i.e., at 20° C.) and is adapted to be transferred to the wearer’s skin” (Roe, col. 2, ll. 62-65).

8. Roe discloses that its lotion compositions comprise “(1) an emollient(s); (2) an immobilizing agent(s) for the emollient; (3) optionally a hydrophilic surfactant(s); and (4) other optional components” (*id.* at col. 10, ll. 20-23).

9. Roe discloses that “[e]mollients useful in the present invention can be petroleum-based” (*id.* at col. 10, ll. 60-61).

10. Roe discloses that “[s]uitable petroleum-based emollients include those hydrocarbons, or mixtures of hydrocarbons, having chain lengths of from 16 to 32 carbon atoms. Petroleum based hydrocarbons having these chain lengths include . . . petrolatum.” (*Id.* at col. 10, l. 63 to col. 11, l. 2.)

11. Roe discloses that the “lotion composition can comprise from about 10 to about 95% of the emollient” (*id.* at col. 13, ll. 5-6).

12. Roe discloses that “ingredients that can be used as immobilizing agents, either alone, or in combination with [other] immobilizing agents, include waxes such as carnauba, beeswax, candelilla, paraffin, Preferably the wax is a paraffin wax.” (*Id.* at col. 16, ll. 36-41.)

13. Roe discloses that the “lotion composition can comprise from about 5 to about 90% of the immobilizing agent” (*id.* at col. 16, ll. 50-51).

14. Roe discloses that “[s]uitable nonionic surfactants . . . will typically have HLB values in the range of from about 4 to about 20” (*id.* at col. 17, ll. 21-25).

15. Roe discloses that suitable nonionic surfactants include “ethoxylated sorbitan mono-, di- and/or tri-esters of C₁₂ to C₁₈ fatty acids having an average degree of ethoxylation of from about 2 to about 20 . . . such as TWEEN 60 . . . and TWEEN 61” (*id.* at col. 17, ll. 37-42) and “ICI’s class of Brij surfactants” (*id.* at col. 18, ll. 10-11).

16. Roe discloses that the “lotion composition can comprise from about 1 to about 50% of the hydrophilic surfactant when needed to increase the wettability properties of the composition” (*id.* at col. 18, ll. 35-37).

17. Roe discloses that the lotion composition “can comprise other optional components typically present in emollient, creams, and lotions of

this type. These optional components include water, viscosity modifiers, perfumes, disinfectant antibacterial actives, pharmaceutical actives,” etc. (*id.* at col. 18, ll. 43-47).

18. Johansson discloses a composition that can be “used in a protective and/or a therapeutic topical barrier formulation for the treatment of dermatological disorders induced by allergens and skin irritating agents” (Johansson, col. 6, ll. 46-48) or “used in a protective and/or therapeutic antiviral, antifungal and/or antiinflammatory formulation for the treatment of dermatological disorders” (*id.* at col. 6, ll. 57-59).

19. Johansson discloses that “a cationic, hydrophilic polymer and an anionic scavenger substance, bound together by either ionic or covalent bonds, have a unique capacity to scavenge or capture body-foreign substances . . . when applied to the skin and mucosa of human beings and animals” (*id.* at col. 6, l. 67 to col. 7, l. 6).

20. Johansson discloses that “[a]lternatively, the cationic, hydrophilic polymer has the ability to separately capture body foreign substances” (*id.* at col. 7, ll. 6-8).

21. Johansson discloses that the “cationic, hydrophilic amine containing polymer . . . is chosen from the group consisting of native chitosan and derivatives thereof having a cationic character” (*id.* at col. 8, ll. 3-6).

22. Johansson discloses that “previous skin healing properties of chitosan products . . . include healing effects on burns, wound healing, tissue regeneration . . . , bacteriostatic, antiviral and antimycotic effects and immunostimulating activity” (*id.* at col. 11, ll. 38-42).

23. Johansson discloses that the “concentration of the cationic, hydrophilic amino-containing polymer, used in . . . the skin protective compositions of this invention, i.e. both the topical barrier formulation and the UV radiation absorbing formulation, range from 0.05 up to 15 weight percent” (*id.* at col. 15, l. 66 to col. 16, l. 4).

24. Johansson discloses that treatment effects of “the basic active principles of the medical composition according to the present invention . . . cover prevention and/or treatment of dermatologic skin disorders, such as herpes infections, fungal infections and psoriasis” (*id.* at col. 18, ll. 16-21).

25. Johansson discloses that the “topical barrier formulation . . . is preferably dermally administered on the skin in the form of a cream, an ointment, a gel, or an oil” (*id.* at col. 19, ll. 35-37).

26. Johansson discloses that the “antiviral, antifungal and antiinflammatory formulation . . . is preferably administered dermally, ophthalmically, on the lips, or in the mucous membrane-anal region and the vulvo-vaginal region, in the form of a cream, an ointment, a gel, a liniment, a lotion,” etc. (*id.* at col. 19, ll. 43-48).

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007).

However,

it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does . . . because inventions in most, if not all, instances rely

upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418-419.

The obviousness analysis “can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418.

Analysis

Roe discloses a composition that meets all the limitations of claim 1 except that it does not include a skin care active comprising chitosan. Johansson discloses a composition comprising chitosan that can be used as a topical barrier to prevent contact of skin with allergenic or irritating substances or for prevention or treatment of viral or fungal infections. It would have been obvious to include Johansson’s chitosan-containing skin care active in Roe’s lotion composition because Roe suggests including pharmaceutical actives in its composition, and Johansson teaches that its chitosan-containing active prevents contact of skin with allergens and irritating substances, and prevents or treats viral infections, fungal infections, and inflammation.

Appellants argue that Johansson teaches that chitosan is a skin protector and “[t]here can be no possible motivation to combine a skin protector (i.e., the chitosan of Johansson) with a lotion that already has a skin protector (i.e., the paraffin wax of Roe)” (Appeal Br. 5).

This argument is not persuasive. Roe discloses that its lotion can contain 10-95% petrolatum (paraffin wax) as an emollient (FFs 6, 10, 11) or 5-90% paraffin wax as an immobilizing agent (FFs 12, 13). Roe does not

teach that either its emollient or immobilizing agent has the effect of preventing skin contact with allergens and irritating substances, or preventing or treating viral or fungal infections, or inflammation. Thus, a person of ordinary skill in the art would have reasonably expected that addition of Johansson's skin care active containing chitosan would contribute desirable properties to Roe's lotion.

Appellants also argue that "Johansson does not disclose chitosan as a skin care active" (Appeal Br. 6) but the Specification expressly states that chitosan is a skin care active (FF 3) regardless of whether Johansson characterizes it as such. In addition, the Specification states that skin care actives include antimicrobials, and Johansson states that its chitosan-containing actives have antiviral and antifungal activity.

Appellants also argue that the Examiner has not shown that the cited references would have suggested the dispensing means recited in claim 14 (Appeal Br. 7). We agree with the Examiner (Answer 6), however, that Roe teaches a dispensing means; specifically, a diaper. (*Cf. Spec. 21: 23-24: "In one embodiment, the dispensing means is one or more components of an absorbent article . . ."*)

Finally, Appellants argue that the references do not suggest the steps of "'applying' by a dispensing means and 'exposing to moisture'" (Appeal Br. 8). We agree with the Examiner that these limitations are reasonably suggested by Roe's disclosure that the lotion composition is applied to a diaper and adapted to be transferred to a wearer's skin. As the Examiner pointed out, "when an infant wears the diaper containing the lotion composition of Roe, the composition on the diaper is exposed to . . .

moisture from the infant's skin or the moisture from the bowel materials'" (Answer 7-8).

Conclusions of Law

The Examiner did not err in concluding that it would have been obvious to a worker of ordinary skill to combine Johansson's skin care active comprising chitosan with Roe's composition.

SUMMARY

We affirm the rejection of claims 1-9 and 11-19 as obvious in view of Roe and Johansson.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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